UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHARON SMITH,

Plaintiff,

v.

COVIDIEN LP,

Defendant.

1:19-cv-11981-NLH-AMD

OPINION

APPEARANCES:

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On behalf of Plaintiff

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On behalf of Defendant

HILLMAN, District Judge

This matter concerns claims by Plaintiff arising from injuries she allegedly sustained from Defendant's surgical mesh used to repair Plaintiff's hernia. For the reasons stated below, Defendant's motion will be granted in part and denied in part.

I. BACKGROUND

On November 11, 2016, Plaintiff, Sharon Smith, underwent a laparoscopic incarcerated incisional and umbilical hernia repair

procedure using Symbotex Mesh in Plaintiff's abdomen to reinforce tissue affected by a hernia. Symbotex Mesh is manufactured and sold by Defendant Covidien LP.

Plaintiff claims that within a few weeks of surgery, she suffered from abdominal pain, swelling, drainage from the wound site, and other complications, which required three subsequent surgeries on December 1, 3, and 5, 2016. The surgeries included removal of infected mesh, drainage of abscess, abdominal washout, and necrotic tissue debridement. She was also found to have ischemic (restricted blood flow) tissue as well as purulent drainage from the right lateral edge of the wound. Plaintiff claims that she has experienced, and continues to experience, debilitating abdominal pain since the implant of the Symbotex Mesh and the multiple surgeries since the implantation of the Symbotex Mesh.

Plaintiff has advanced claims under the New Jersey Product Liability Act ("PLA") for defective design, defective manufacture, and failure-to-warn. Plaintiff has also brought claims under New Jersey common law for negligence, breach of the implied warranty of fitness for a particular purpose, breach of express warranty, as well as a claim for punitive damages.

Defendant has moved to dismiss Plaintiff's complaint in its

entirety. Defendant argues that Plaintiff's common law claims for negligence and breach of the implied warranty are subsumed within the PLA and must be dismissed. Defendant also argues that Plaintiff has failed to properly plead her claims brought under the PLA and for breach of the express warranty. Finally, Defendant argues that Plaintiff's count for punitive damages is derivative and cannot survive where the substantive claims fail as a matter of law. Plaintiff has opposed Defendant's motion.

II. JURISDICTION

This Court exercises jurisdiction pursuant to 28 U.S.C. § 1332(a), diversity of citizenship. Plaintiff is a citizen of New Jersey. Defendant is a limited partnership with limited liability companies and corporations as its members, none of which are citizens of New Jersey. (See Docket No. 6 at 2-3.) The amount in controversy exceeds $75,000 exclusive of interest and costs.

III. DISCUSSION

A. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept all well-pleaded allegations in the complaint as

true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original) (citations omitted) (first citing Conley v. Gibson, 355 U.S. 41, 47 (1957); Sanjuan v. Am. Bd. of Psychiatry & Neurology, Inc., 40 F.3d 247, 251 (7th Cir. 1994); and then citing Papasan v. Allain, 478 U.S. 265, 286 (1986)).

To determine the sufficiency of a complaint, a court must take three steps: (1) the court must take note of the elements a plaintiff must plead to state a claim; (2) the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth; and (3) when there are well-pleaded factual allegations, a court

should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief. Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 664, 675, 679 (2009) (alterations, quotations, and other citations omitted).

A district court, in weighing a motion to dismiss, asks "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim." Twombly, 550 U.S. at 563 n.8 (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Iqbal, 556 U.S. at 684 ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail in the coffin for the 'no set of facts' standard that applied to federal complaints before Twombly."). "A motion to dismiss should be granted if the plaintiff is unable to plead 'enough facts to state a claim to relief that is plausible on its face.'" Malleus, 641 F.3d at 563 (quoting Twombly, 550 U.S. at 570).

A court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice.

S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

B. Plaintiff's claims under the PLA

Under the New Jersey Product Liability Act (PLA),

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C-2.

The cited statutory text establishes three causes of action under the PLA: (1) design defect, (2) manufacturing defect, or (3) warnings defect. Mendez v. Shah, 28 F. Supp. 3d 282, 296

(D.N.J. 2014) (citing Roberts v. Rich Foods, Inc., 139 N.J. 365, 375, 654 A.2d 1365 (N.J. 1995); Dziewiecki v. Bakula, 361 N.J. Super. 90, 97-98, 824 A.2d 241 (App. Div. 2003)). The standard of liability is that the product "was not reasonably fit, suitable or safe for its intended purpose." Id. (citing Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 998 A.2d 543 (App. Div. 2010)). The "mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." Id. (citation omitted).

Defendant takes the position that hernia mesh products are generally reliable and have been used successfully for many years in hundreds of thousands of surgeries. Moreover, it contends that the Symbotex mesh product at issue has not been subject to any recalls, withdrawals, or adverse regulatory action, and that the alleged complications from Plaintiff's surgery are common side-effects disclosed in the product's Instructions for Use. Under these circumstances, Defendant contends, Plaintiff cannot maintain her claims that the Symbotex mesh was defectively designed, improperly manufactured, or Defendant should have warned her of the product's dangers. In short, Defendant argues that Plaintiff has not, and cannot, plead any facts to support her claims that the Symbotex mesh

used to repair Plaintiff's hernia was not "reasonably fit, suitable or safe."

Contrary to Defendant's view of Plaintiff's claims, while Plaintiff's complaint is admittedly thin it does not assert in conclusory fashion that simply because Plaintiff suffered complications from the surgical use of Symbotex mesh it must be because the product was defective in some fashion. The Court concludes that, at this pleading stage, Plaintiff has alleged enough facts to establish the plausibility of her three claims under the PLA.

1. Defective Design

In determining whether a product was defectively designed, courts apply a risk-utility analysis. Lopez v. Borough of Sayreville, 2008 WL 2663423, at *25 (N.J. Super. Ct. App. Div. 2008), cert. denied, 960 A.2d 395 (N.J. 2008) (citing Cavanaugh v. Skil Corp., 164 N.J. 1, 8, 751 A.2d 518 (2000); Lewis v. American Cyanamid Co., 715 A.2d 967, 980 (N.J. 1998)). "A plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." Id. (citing Lewis, 715 A.2d at 980).

There are seven listed factors in the classical statement

of the risk-utility analysis,[1] but the prevalent view is that unless one or more of the other factors might be relevant in a particular case, the issue upon which most claims will turn is the proof by plaintiff of a reasonable alternative design, the omission of which renders the product not reasonably safe.

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[1] The seven listed factors in the classical statement of the risk-utility analysis are:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. (Ordinarily, a consideration only for the court.)

Grier v. Cochran Western Corp., 705 A.2d 1262, 1269 n.4 (N.J. Super. Ct. App. Div. 1998).

Cavanaugh v. Skil Corp., 751 A.2d 518, 522 (N.J. 2000) (citation omitted). The burden is on the plaintiff to prove "the existence of an alternative design that is both practical and feasible" and "safer" than that used by the manufacturer. Lopez, 2008 WL 2663423 at *25 (citing Lewis, 715 A.2d at 980) ("Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible.").

Generally, the factfinder is required to perform a risk-utility analysis in order to determine whether a product is defective in its design, and in performing a risk-utility analysis, an expert opinion is ordinarily relied upon to establish a reasonable alternative design. Rocco v. New Jersey Transit Rail Operations, Inc., 749 A.2d 868, 879 (N.J. Super. Ct. App. Div. 2000). "Except in the rare case when the risk-utility analysis points to the appropriate result as a matter of law, the jury, not the court, ultimately resolves factual issues arising from a risk-utility analysis." Lewis, 715 A.2d at 979 (citing Dreier et al., *Current N.J. Products Liability and Toxic Torts Law*, § 5.2 at 29 (1998)); see also Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 124 (3d Cir. 2008) (citations

omitted) ("[T]he existence of a design defect is frequently proven through the testimony of an expert who has examined the product and offers an opinion on its design.").

Here, Plaintiff alleges in her complaint:

- Symbotex mesh is a "three-dimensional textile non-absorbable monofilament polyester mesh with absorbable collagen film and marking."
- Issues with polyester concern "the terminal product in a chain of very reactive and toxic precursors. Most are carcinogens; all are poisonous," and polyester is increasingly toxic because it is often treated with a flame retardant.
- These components are alleged to cause issues where: "the collagen film fails to mitigate the body's adverse reaction to the non-absorbable polyester mesh"; "polyester is prone to tearing, ripping, and/or fraying" and "once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body," which cause imbedding and an inflammatory response; and "polyester mesh contracts over time, causing tension to increase."
- The collagen barrier dissolves, and when it does, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.
- Both polycarbonate and polystyrene are reasonable alternative designs which are less dangerous and equally, if not more, effective than polyester.
- The defective design was a proximate cause of Plaintiff's injuries.

(Docket No. at 20-22.)

Defendant argues that these allegations are not sufficient to state a design defect claim because Plaintiff fails to plead

any facts to answer the questions of "What is it about collagen that causes it to 'fail[] to mitigate the body's adverse reaction'?" or "[W]hat is it about polyester that causes an 'adverse reaction,' and what type of 'adverse reaction' does it cause?" or "What are the characteristics of polyester that make it 'prone to tearing and ripping and/or fraying'?" (Docket No. 16 at 9-10.) Additionally, Defendants argue that Plaintiff has not alleged that these defects caused her injuries, particularly because her alleged injuries can be suffered with any mesh product. Defendant further argues that Plaintiff has not sufficiently pleaded a safer alternative design, other than to conclude that polycarbonate and polystyrene "are less dangerous and equally, if not more, effective than polyester." (Id. at 10-11.)

Defendant's arguments demonstrate why the law provides that "the jury, not the court, ultimately resolves factual issues arising from a risk-utility analysis." Lewis, 715 A.2d at 979. Defendant's arguments also show why, when a "case involves a complex instrumentality, expert testimony is needed in order to help the fact-finder understand 'the mechanical intricacies of the instrumentality' and help to exclude other possible causes of" the plaintiff's injuries. Rocco, 749 A.2d at 879.

Plaintiff has alleged that the use of polyester in Symbotex's design was defective and caused her injuries, while mesh made with polycarbonate and polystyrene are more practical, safer, and are reasonable alternative designs. The Court has no reason to believe or doubt the truth of this allegation nor is that for this Court to determine. Ultimately it will be Plaintiff's burden, through the use of expert testimony, to prove her design defect allegations to a factfinder, which will perhaps require Plaintiff to respond to Defendant's questions, as well as respond to their argument that Plaintiff merely suffered from known side-effects from a properly designed product. Plaintiff cannot be faulted at this pleading stage, however, for not having all the answers, particularly because Defendant may be in possession of information Plaintiff needs to prove her claims, and because an expert is necessary to articulate the basis for Plaintiff's defective design claim. In short, Plaintiff has alleged a plausible design defect claim, the substantive merit of which will be assessed at a later stage in the case.[2]

[2] Defendant requests that this Court follow decisions of the Southern District of New York, which assessed the sufficiency of plaintiffs' claims regarding injuries they sustained from polyester hernia mesh products. For example, in Dunham v. Covidien LP, 2019 WL 2461806, at *3 (S.D.N.Y. 2019), the court

2. Defective Manufacture

A manufacturing defect is a "deviat[ion] from the design specifications, formulae, or performance standards of the

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found:

> The allegations in the complaint regarding design defect in this case are conclusory. The complaint alleges that the hernia mesh is dangerous because its delicate collagen film fails to mitigate the body's adverse reaction to the detached polyester. Although the complaint does provide factual support for the allegation that polyester can detach from the mesh and cause harm, it does not allege how the collagen film mitigates or fails to mitigate detached polyester's harmful effects. Nor does the complaint allege any facts to support its assertion that the "defective design was a proximate cause of Plaintiff's injuries," (Compl. ¶ 152), which leaves that to speculation. It does not address the numerous plausible alternative explanations for Mr. Dunham's medical problems, including natural complications from his hernia disease or the development of a new hernia.
>
> Moreover, the complaint does not adequately allege that there was a feasible alternative design that would have made the product safer. It merely alleges that different products like the Shouldice Repair, McVay Repair, Bassini Repair, Desarda Repair, or different materials like polycarbonate or polystyrene, are safer and more effective alternatives to hernia mesh. "However, alleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element."

Dunham, 2019 WL 2461806 at *3.

This Court does not find Dunham or the other out-of-district cases cited by Defendant persuasive. Those cases concern a different state's law and apply a narrower view of Rule 8 and Twombly/Iqbal than this Court deems appropriate on the facts of this case as alleged.

manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae. . . .” N.J.S.A. 2A:58C-2. A product seller shall be liable if it “knew or should have known of the defect in the product which caused the injury, death or damage or the plaintiff can affirmatively demonstrate that the product seller was in possession of facts from which a reasonable person would conclude that the product seller had or should have had knowledge of the alleged defect in the product which caused the injury, death or damage . . . .” N.J.S.A. 2A:58C-9(d)(2).

Under both the design defect and manufacturing theories, plaintiff must prove “that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user.” Schweiger v. Standard Tile Supply, Co., 2019 WL 5783478, at *3 (N.J. Super. Ct. App. Div. Nov. 6, 2019) (quoting Myrlak v. Port Auth., 157 N.J. 84, 97 (1999)). A “plaintiff may not merely rely on the presumption of a defect because of the happening of an accident.” Rybkin v. Township of North Bergen, 2012 WL 1722575, at *8 (N.J. Super. Ct. App. Div. 2012) (citing Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 49 (1996)) (other citation

omitted).

The New Jersey Supreme Court has set forth three means by which a plaintiff can demonstrate the existence of a manufacturing defect: (1) direct evidence that the defect arose in the hands of the manufacturer; (2) circumstantial evidence which would permit an inference that a dangerous condition existed prior to sale; or (3) by negating other causes of the failure of the product for which the defendant would not be responsible, in order to create an inference that the defect was attributable to the manufacturer." Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 125 (3d Cir. 2008))(citing Scanlon v. General Motors Corp., 65 N.J. 582, 326 A.2d 673 (1974)).[3]

Just like a design-defect claim, a claim for manufacturing defect usually requires expert testimony. Id. (citing Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 174 (1979) ("Though

[3] A fourth method of establishing a manufacturing defect is the "indeterminate product defect test," which is limited to those product liability cases in which the plaintiff cannot prove a specific defect. Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 125 (3d Cir. 2008) (citing Restatement (Third) of Torts: Products Liability § 3 (1997), as adopted by Myrlak v. Port Auth. of N.Y. & N.J., 157 N.J. 84, 723 A.2d 45, 55–56 (1999)). ("A plaintiff may also rely on an inference that a product is defective where the incident that harmed the plaintiff was (1) of a kind that ordinarily occurs as a result of a product defect; and (2) was not, in the particular case, solely the result of causes other than a product defect existing at the time of sale or distribution.").

the nature of the proof to demonstrate that the product was defective may differ, the ultimate jury test is the same. Suitability and safety are implicated whether the defect in the product is due to an imperfection in the material or improper design.")); Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 125 (3d Cir. 2008) (explaining that where a product is complex, a plaintiff is required to present expert testimony in order to rule out other likely explanations for the incident) (citing Lauder v. Teaneck Volunteer Ambulance Corps, 368 N.J. Super. 320, 845 A.2d 1271, 1277 (2004) ("[W]here the allegedly defective product involves a complex instrumentality, a plaintiff is required to provide expert testimony.")) (other citations omitted).

Plaintiff is this case alleges:

- The mesh was defective and deviated from manufacturing standards when it came off the product line and failed to perform in its intended manner due to a flaw in the manufacturing process.

- Plaintiff was a reasonably foreseeable user of the mesh product, and as a result of the defective mesh, she suffered serious bodily injuries.

(Docket No. 1 at 22-23.)

Defendant argues that Plaintiff's manufacturing defect claim is conclusory without any facts to support it - simply because she suffered injuries does not mean the mesh was

manufactured defectively. Defendant argues that because Plaintiff has not "negated other causes of the failure of the product for which the defendant would be responsible," Plaintiff's manufacturing defect claims fails. For that proposition, Defendant cites to Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 125, (3d Cir. 2008), which affirmed the district court's grant of summary judgment in the defendant's favor on the plaintiff's manufacturing defect claim.

In response, Plaintiff argues that in addition to pleading the elements of a viable manufacturing defect claim, the nature and severity of Plaintiff's injuries, and the immediacy of them after the surgery, create sufficient circumstantial proof that "something was wrong" with the product, which will be established by Plaintiff's testimony and testimony of an expert. Plaintiff further notes Defendant's position that surgical meshes are safely used in hundreds of thousands of hernia repairs surgeries each year, and argues, "Clearly, if hundreds of thousands of hernia repairs are successfully completed each year, the fact that the Plaintiff was required to undergo three surgeries within a month of the implantation of the Defendant's mesh is circumstantial proof that 'something was wrong' with the mesh." (Docket No. 15 at 11.)

Contrary to Defendant's argument, Plaintiff is not required in her complaint to negate other causes of the failure of the product for which the defendant would be responsible, as that standard is only one method by which Plaintiff can prove her claim. Moreover, unlike other products, like cars or appliances which can be easily examined, it seems next to impossible for Plaintiff, at this stage, to determine with the precision Defendant expects whether - and how - the mesh inside her body was manufactured. Accordingly, and while we view the call a close one, the Court finds that, whether under the "circumstantial evidence" or "indeterminate defect" test, Plaintiff's allegations regarding the nature and severity of the alleged injuries, how quickly they occurred, and the extent of the required post-operative care, when taken together, plausibly suggest that the mesh was defective.

Of course, it could also be that the mesh was not manufactured defectively and, as Defendant points out, Plaintiff only suffered from typical side-effects of a properly manufactured product. Again, Plaintiff has her theory and offered facts to support it which will, at the appropriate time, be put to the test. This Court will not foreclose Plaintiff's manufacturing defect claim at the initial pleading stage when

the nature of the mesh product used to repair Plaintiff's hernia is currently unknowable to her, but the circumstances surrounding of the implantation of the mesh and aftercare plausibly suggest a manufacturing defect.

3. Failure to Warn

The elements for proving a failure-to-warn claim are essentially the same as for a design defect claim. Lopez v. Borough of Sayreville, 2008 WL 2663423, at *15–16 (N.J. Super. Ct. App. Div. 2008) (citing Jurado v. W. Gear Works, 131 N.J. 375, 385, 619 A.2d 1312 (1993)). A plaintiff must prove: (1) the product was defective; (2) the defect existed when the product left the defendant's control; and (3) the defect caused injury to a reasonably foreseeable user. Id. (citing Coffman v. Keene Corp., 133 N.J. 581, 593, 628 A.2d 710 (1993)). In a failure-to-warn case, "the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that the product can potentially cause injury." Id. (citing Clark v. Safety–Kleen Corp., 179 N.J. 318, 336, 845 A.2d 587 (2004)) (other citation omitted). The failure to provide necessary warnings constitutes a breach of duty. Id. (citation omitted).

Initially, the plaintiff must establish that the defendant

had a duty to warn. Id. (citing James v. Bessemer Processing Co., 155 N.J. 279, 297–98, 714 A.2d 898 (1998)). The manufacturer of a product has a duty to warn about any risk relating to the product that it knows or ought to know, unless the risk and the way to avoid it are obvious. Id. (citing Feldman v. Lederle Labs., 97 N.J. 429, 434, 479 A.2d 374 (1984) (other citation omitted). Once plaintiff establishes a duty to warn, she must then establish that an adequate warning was not provided. Id. (citation omitted). A manufacturer "shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction." N.J.S.A. 2A:58C-4.

An "adequate warning" is defined as:

> [O]ne that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used....

N.J.S.A. 2A:58C-4.

"Causation is a fundamental requisite for establishing any product-liability action," and a "plaintiff must demonstrate . . . the defect in the product was a proximate cause of the injury." Lopez, 2008 WL 2663423 at *15–16 (citation omitted).

"Ordinarily, the jury considers issues of proximate cause." Id. (citing Shelcusky v. Garjulio, 172 N.J. 185, 206, 797 A.2d 138 (2002)).

Plaintiff in this case alleges:

- Defendant owed a duty to Plaintiff and Plaintiff's physicians to communicate and provide a comprehensive briefing, in layman's terms, as to what exactly was being implanted in her peritoneal cavity, including the exact material composition of the mesh, the lack of flexibility of the mesh, how the mesh was to be deployed and attached and the overall adverse reactions that the foreign material could cause in her body.

- The warnings that were provided by Defendant regarding its hernia mesh product were ambiguous or were not sufficient, accurate or clear.

- Defendant provided a very generic and ineffective way to express mesh product failures to patients and doctors.

- At no time was Plaintiff warned of the "possible complication" that actually occurred, including burning pain, abdominal drainage from the wound, sepsis, formation of an abscess and ischemic tissue.

- Defendant's failure to comply with its duty to warn Plaintiff and her doctors of the dangers associated with its hernia mesh product resulted in Plaintiff's injuries.

(Docket No. 1 at 24-26.)

Defendant argues that Plaintiff's failure-to-warn claim fails because she does not specify which warning was inadequate, especially considering that Symbotex's Instructions for Use warn about the very complications Plaintiff allegedly suffered, and

of which she was aware.[4]

The Court does not agree. The fundamental basis for Defendant's argument is that its warning was adequate because it revealed the side-effects Plaintiff incurred. Plaintiff, however, claims that she was not warned about what actually occurred, including burning pain, abdominal drainage from the wound, sepsis, formation of an abscess and ischemic tissue.

The Court concludes, somewhat reluctantly, that Plaintiff has sufficiently stated a failure-to-warn claim. Plaintiff claims she was not warned about complications she experienced, and she should have been. Defendant claims that Plaintiff was

[4] In a footnote, Defendant also contends that the learned intermediary doctrine bars Plaintiff's failure-to-warn claim. The doctrine holds that the prescribing physician - as a learned intermediary - generally is in the best position to advise the patient of the benefits and risks of taking a particular drug to treat a medical condition. In re Accutane Litigation, 194 A.3d 503, 524 (N.J. 2018) (citation omitted). In the case of prescription drugs, the PLA codifies the learned intermediary doctrine, and a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities. Id. (citing N.J.S.A. 2A:58C-2) (other citations omitted). The resolution of whether the doctrine is applicable in this case, and if it is, whether it defeats Plaintiff's failure-to-warn claim, cannot be resolved through the instant motion to dismiss. See Hindermyer v. B. Braun Medical Inc., 2019 WL 5881073, at *11 n.4 (D.N.J. 2019) ("Determining whether a prescribing physician was given sufficient warning in connection with a defendant's medical product pursuant to the learned intermediary doctrine raises factual questions that generally cannot be resolved on an undeveloped record.").

properly warned about pain and infection. The Court's reluctance stems from the failure of the Defendant to point out with sufficient clarity which portion of the lengthy warnings provided to Plaintiff constitute adequate warning of the injuries she alleges she sustained.

The Court recognizes that Plaintiff has the burden of alleging facts sufficient to make out plausible claim but in light of the apparent complexity and length of the warnings - which neither side has provided to the Court in legible form[5] – the Defendant would seem to have a ready remedy. More specifically, where a claim is based on an indisputably authentic document, Defendant may base a complete defense on language in that document. Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

In the context of this case, all the Defendant need do is point to that portion of the warnings that describes Plaintiff's alleged injuries with sufficient fidelity. It is generally easier to prove an existential fact than a universal truth. Yet Defendant does not proffer that defense with the requisite specificity but simply replies to Plaintiff's broad assertion

[5] Defendant provides a copy of the product's Instruction for Use through a certification of counsel but the copy is in such small type as to be unreadable.

the warnings did not adequately describe her actual experience (e.g., "burning pain") with the equally broad claim that the warning are adequate (e.g., "pain").[6] Under such circumstances the Court is constrained to allow to the failure-to-warn claim to proceed for the factfinder to resolve.

C. Plaintiff's claims for negligence and breach of implied warranty

In addition to her PLA claims, Plaintiff claims that Defendant was "negligent in designing, manufacturing, and selling hernia mesh products" (Docket No. 1 at 26), and that Defendant impliedly warranted "that its hernia mesh product was reasonably fit for its intended use and that it was designed, manufactured, and sold in accordance with good design, engineering, and industry standards" (Docket No. 1 at 28).

These claims are subsumed by the PLA and must be dismissed. See Hindermyer v. B. Braun Medical Inc., 2019 WL 5881073, at *4 (D.N.J. Oct. 30, 2019) (citing cases) ("In recognition of the broad scope of the NJPLA, New Jersey federal and state courts

[6] Defendant also offers the defense that the Food and Drug Administration through its website warns consumers about the risks associated with the surgical repair of hernias. Defendant does not explain, however, how a statement on a government website acts as a complete defense to a claim that the warnings that accompany a private company's medical device are inadequate.

have consistently dismissed product liability-related claims based on common law theories when at the heart of those theories is the potential 'harm caused by a product.'"); Mendez v. Shah, 28 F. Supp. 3d 282, 287 (D.N.J. 2014) (citing N.J.S.A. 2A:58C–1(b)(3); Hart v. Medtronic, Inc., 2017 WL 5951698, at *3 (D.N.J. 2017) (quoting In re Lead Paint Litig., 191 N.J. 405, 436–47, 924 A.2d 484 (2007)) (explaining that the PLA subsumes any cause of action "for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty," and those former common-law causes of action (with the exception of breach of express warranty) have merged into a single cause of action under the PLA"); Fidelity and Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc., 936 F. Supp. 2d 441, 447 (D.N.J. 2013) ("[T]he PLA does not recognize either negligence or implied breach of warranty as separate claims for harm caused by a defective product; those claims have been subsumed within the new statutory cause of action."); Worrell v. Elliott & Frantz, 799 F. Supp. 2d 343, 351 (D.N.J. 2011) ("Since the passage of the PLA, New Jersey courts have repeatedly held that claims of negligent manufacture and breach of implied warranty are no longer viable as separate causes of action for harm caused by a product." (citing Port

Auth. of N.Y. & N.J. v. Arcadian Corp., 189 F.3d 305, 313 (3d Cir. 1999) ("Under New Jersey law negligence is no longer viable as a separate claim for harm caused by a product.")).

D. Plaintiff's claim for breach of express warranty

The PLA does not subsume a plaintiff's claim for breach of express warranty. N.J.S.A. 2A:58C-1(b)(3) ("'Product liability action' means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.").

To state a claim for breach of express warranty under New Jersey law, a plaintiff must allege the following three elements: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Companies, Inc., 792 F. Supp. 2d 712, 721 (D.N.J. 2011).

Under the New Jersey U.C.C., N.J.S.A. 12A:2-313, an "express warranty" is:

> (1) Express warranties by the seller are created as follows:
>
> (a) Any affirmation of fact or promise made by the seller

> to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. 12A:2-313.

"A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance." Volin v. General Electric Company, 189 F. Supp. 3d 411, 420 (D.N.J. 2016) (citations omitted). "[S]tatements that are nothing more than mere puffery are not considered specific enough to create an express warranty." Snyder, 792 F. Supp. 2d at 721.

"Under New Jersey law, a representation is presumed to be part of the basis of the bargain 'once the buyer has become aware of the affirmation of fact or promise' and can be rebutted by 'clear affirmative proof that the buyer knew that the affirmation of fact or promise was untrue.'" Volin, 189 F. Supp. 3d at 420 (citing Viking Yacht Co. v. Composites One LLC,

496 F. Supp. 2d 462, 469 (D.N.J. 2007) (quoting Liberty Lincoln–Mercury, Inc. v. Ford Motor Co., 171 F.3d 818, 825 (3d Cir. 1999) (internal quotation omitted)).

Plaintiff's complaint alleges:

- Defendant expressly warranted to Plaintiff and Plaintiff's physician that its product was safe and effective for the use of hernia repair.
- Plaintiff and her doctor relied upon this express warranty.
- Defendant represented that its Symbotex mesh was "designed to match the surgeon's demands for ease of handling, operative efficiency, versatility, and demonstrated equivalent performance as Parietex composite and Parietex optimized composite mesh," and that it "provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair."
- Defendant warranted that its product had "innovative mesh features for streamlined performance; smart handling experience simplicity in hernia repair; smart repair designed to offer patients optimal hernia repair performance," and that the mesh provided "excellent tissue integration minimized visceral attachment good level of neoperitonization and better minimizing tissue attachment helping to meet physiological needs through balanced mesh mechanical properties."
- Defendant's mesh was defective in its design and manufacture.
- Defendant breached its express warranties regarding the Symbotex mesh, which caused Plaintiff's injuries.

(Docket No. 1 at 28-30.)

Defendant argues that Plaintiff's breach of express

warranty claim fails because it does not contain any factual content detailing how the statements were made, who heard the statements, when and where the alleged express warranties were made, or how any of the purported false statements made to Plaintiff or her physician became part of the basis of the bargain.

While that level of detail would be helpful in joining the issues in the case, and will no doubt be addressed in discovery, Defendant has cited no authority for the proposition that these deficiencies are required at the pleading stage. The detail that is provided states expressly the language of the alleged warranty and to whom the statements were made, including Plaintiff's doctor who could be fairly be said part of the bargain of providing medical services, and in the context of the pleading as whole, contrasts the language with the alleged injuries and asserts causation. In short, Plaintiff has provided sufficient facts to support the elements of a breach of express warranty under New Jersey law. This claim may proceed.

E. Punitive Damages

Plaintiff asserts a stand-alone claim for punitive damages. (Count III, Docket No. 1 at 30.) Defendant has moved to dismiss Plaintiff's punitive damages count because it is derivative of

her other claims - that is, because her other claims fail, she cannot maintain a claim for punitive damages. Defendant also argues that the conduct alleged by Plaintiff does not rise to the level that supports a finding of punitive damages.

The Court will not dismiss Plaintiff's request for punitive damages for either of the reasons argued by Defendant. The Court must dismiss Plaintiff's separate count for punitive damages, however, because an independent count for punitive damages is not cognizable. DiAntonio v. Vanguard Funding, LLC, 111 F. Supp. 3d 579, 585 (D.N.J. 2015) (citing Hassoun v. Cimmino, 126 F. Supp. 2d 353, 372 (D.N.J. 2000) ("Punitive damages are a remedy incidental to [a] cause of action, not a substantive cause of action in and of themselves.").

Plaintiff is not prevented from seeking punitive damages relative to her other claims if punitive damages are available for such claims. See, e.g., Zodda v. National Union Fire Ins. Co. of Pittsburgh, Pa., 2014 WL 1577694, at *5 (D.N.J. 2014) ("It is well settled that that the general rule is that there is no[] cause of action for 'punitive damages.' This count will be dismissed from the complaint, but the Court notes that Plaintiff has preserved its right to argue for punitive damages as a remedy if allowed under the remaining causes of action."); cf.

Gross v. Gynecare, 2016 WL 1192556, at *26 (N.J. Super. Ct. App. Div. 2016) ("[T]he PLA only bars punitive damages for devices with premarket approval."); Batchelor v. Procter & Gamble Co., 2014 WL 6065823, at *6 (D.N.J. 2014) (citing N.J.S.A. 2A:58C–5(c)) ("The PLA generally prohibits the award of punitive damages," but the "statute contains one exception. That exception permits a plaintiff to seek punitive damages 'where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the [FDA's] regulations.'").

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss will be granted as to Plaintiff's claims for negligence and breach of implied warranty, and for Plaintiff's stand-alone claim for punitive damages.[7] Defendant's motion will be denied

[7] In her opposition to Defendant's motion, Plaintiff requests leave to file an amended complaint if the Court were to dismiss any of her claims. The Court will deny Plaintiff's request because it would be futile to replead her claims for negligence and breach of implied warranty, and her stand-alone claim for punitive damages. Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)) (explaining that leave to file an amended complaint should not be afforded where there is undue delay, bad faith, dilatory motive, unfair prejudice, or futility of amendment).

as to Plaintiff's claims under the Product Liability Act and for breach of the express warranty.

An appropriate order will be entered.

Date: December 31, 2019
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.